PTO/SB/21 (08-03) Approved for use through 08/30/2003. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE ction of information unless it displays a valid OMB control number. perwork Reduction Act of 1995, no persons are required to respond to Application Number 09/816,790 TRANSMITTAL Filing Date March 22, 2001 **FORM** First Named Inventor Keith D. Allen Art Unit (to be used for all correspondence after initial filing) 1636 Examiner Name Celine X. Qian Attorney Docket Number R-855 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance communication V Fee Transmittal Form Drawing(s) to Technology Center (TC) Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Proprietary Information

Status Letter
Other Editorec(s) (please Identify below) Appeal Communication to TC ~ Petition Amendment/Reply Petition to Convert to a After Final Provisional Application Power of Attorney, Revocation Affidavits/declaration(s) Change of Correspondence Address Terminal Disclaimer Extension of Time Request Request for Refund Express Abandonment Request CD, Number of CD(s) Information Disclosure Statement Remarks Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Kelly L. Quast, Reg. No. 52,141 Individual name Signature duant Date 09/22/03 CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with

sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name Don Mixon Date 09/22/03 Signature

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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₹ TBA	FEE TRANSMITTAL	_
	for FY 2003	

Effective 01/01/2003. Patent fees are subject to annual revision.

✓ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

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Complete if Known				
Application Number	09/816,790	17 0		
Filing Date	March 22, 2001		Š	
First Named Inventor	Keith D. Allen	OCT		
Examiner Name	Celine X. Cil.	OR		
Art Unit	1636	END	2000	
Attorney Docket No.	R-855	150		

METHOD OF PAYMENT (check all that apply)	F	FEE CALCULATION (continued)	200
Check Credit card Money Other None	3. ADDITIONAL F	EES	
Deposit Account:	arge Entity Small En	ntity	
Denosit	Fee Fee Fee Code (\$)		Ean Doid
Account Number 50-1271	(,,	65 Surcharge - late filing fee or oath	Fee Paid
Deposit Account Deltagen, Inc.		25 Surcharge - late provisional filing fee or cover sheet	
Name The Director is authorized to: (check all that apply)	1053 130 1053 13	30 Non-English specification	
Charge fee(s) indicated below Credit any overpayments	1812 2,520 1812 2,52	20 For filing a request for ex parte reexamination	
Charge any additional fee(s) during the pendency of this application	1804 920* 1804 92	20* Requesting publication of SIR prior to Examiner action	
Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.	1805 1,840* 1805 1,84	40* Requesting publication of SIR after Examiner action	
FEE CALCULATION	1251 110 2251 5	55 Extension for reply within first month	205.00
1. BASIC FILING FEE	1252 410 2252 2	205 Extension for reply within second month	205.00
Large Entity Small Entity	1253 930 2253 4	465 Extension for reply within third month	-
Fee Fee Fee Fee Paid Code (\$) Code (\$)	1254 1,450 2254 7	725 Extension for reply within fourth month	
1001 750 2001 375 Utility filing fee	1255 1,970 2255 9	985 Extension for reply within fifth month	
1002 330 2002 165 Design filing fee	1401 320 2401 1	160 Notice of Appeal	
1003 520 2003 260 Plant filing fee	1402 320 2402 1	160 Filing a brief in support of an appeal	
1004 750 2004 375 Reissue filing fee	1403 280 2403 1	140 Request for oral hearing	
1005 160 2005 80 Provisional filing fee	1451 1,510 1451 1,5	510 Petition to institute a public use proceeding	
SUBTOTAL (1) (\$)	1452 110 2452	55 Petition to revive - unavoidable	
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	1453 1,300 2453 6	650 Petition to revive - unintentional	
Fee from	' I	650 Utility issue fee (or reissue)	
Total Claims		235 Design issue fee	
Independent 2** - V		315 Plant issue fee	
Claims -3		130 Petitions to the Commissioner	
Large Entity Small Entity	1807 50 1807	50 Processing fee under 37 CFR 1.17(q)	
Fee Fee Fee Fee Fee Description Code (\$) Code (\$)	1806 180 1806 1 8021 40 8021	180 Submission of Information Disclosure Stmt 40 Recording each patent assignment per	
1202 18 2202 9 Claims in excess of 20		property (times number of properties)	
1201 84 2201 42 Independent claims in excess of 3	1809 750 2809 3	375 Filing a submission after final rejection (37 CFR 1.129(a))	
1203 280 2203 140 Multiple dependent claim, if not paid	1810 750 2810 3	375 For each additional invention to be examined (37 CFR 1.129(b))	
1204 84 2204 42 ** Reissue independent claims over original patent	1801 750 2801 3	375 Request for Continued Examination (RCE)	
1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent		900 Request for expedited examination of a design application	
SUBTOTAL (2) (\$)	Other fee (specify)		
**or number previously paid, if greater; For Reissues, see above	*Reduced by Basic Filing	ng Fee Paid SUBTOTAL (3) (\$) 205.0	0

(Complete (if applicable)) SUBMITTED BY Registration No. Name (Print/Type) Kelly L. Quast 52,141 Telephone 650-569-5100 (Attorney/Agent) celly fluant Date 09/22/03 Signature

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APPLICATION NO. FILING DATE		THOS TO THE STATE OF THE STATE		ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,790		03/22/2001	Keith D Aller	R-855	5557
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740 BAY ROAD REDWOOK CITY, CA 94063			SEP 2 6 2003 P	QIAN, CE	ELINE X
			THE TRACEMENT OF	ART UNIT	PAPER NUMBER
			HADE	1636	<u> </u>
				DATE MAILED: 04/21/2003	

- Please find below and/or attached an Office communication concerning this application or proceeding.

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*Coc		Application No.	Applicant(s)
mag "k		Application No.	
2 6 7000		09/816,790	ALLEN ET AL.
TRACE The	fice Action Summary	Examiner	Art Unit
TRADENTE		Celine X Qian	1636
<i>Th</i> e Period for Rep		ation appears on the cover sheet w	ntn the correspondence address
THE MAILIN - Extensions of after SIX (6) N - If the period fi - If NO period fi - Failure to rep - Any reply reco	NG DATE OF THIS COMMUNIC time may be available under the provisions of MONTHS from the mailing date of this communior reply specified above is less than thirty (30) by reply is specified above, the maximum status the color of the color of the provision for reply well as the color of the provision for reply well as the color of the provision for reply well as the color of the provision for reply well as the color of the provision for reply well as the provision for reply well as the provision for reply well as the provision for t	737 CFR 1.136(a). In no event, however, may a nication.	reply be timely filed rly (30) days will be considered timely. NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).
. 1)⊠ Res	consive to communication(s) file	d on <u>04 March 2003</u> .	
2a)☐ This	action is FINAL.	b)⊠ This action is non-final.	
3)☐ Sind clos Disposition of	ed in accordance with the practic	for allowance except for formal ma ce under <i>Ex parte Quayle</i> , 1935 C	atters, prosecution as to the merits is .D. 11, 453 O.G. 213.
•	n(s) <u>11-16,22-25 and 40-51</u> is/a	re pending in the application.	
		22-25 is/are withdrawn from consid	deration.
	n(s) <u>40-43 and 50</u> is/are allowed		
• —	n(s) <u>44-49, 51</u> is/are rejected.		
7)☐ Clain	n(s) is/are objected to.		
8) Clain	n(s) are subject to restrict	ion and/or election requirement.	
Application Pa	apers		
9)∐ The s	pecification is objected to by the	Examiner.	
10)⊠ The d	rawing(s) filed on 22 March 200	<u>1</u> is/are: a)⊠ accepted or b)⊡ obje	cted to by the Examiner.
		ection to the drawing(s) be held in abe	
11) <u></u> The p	roposed drawing correction filed	on is: a) approved b)	disapproved by the Examiner.
lf a _l	oproved, corrected drawings are req	uired in reply to this Office action.	
12)∏ The o	ath or declaration is objected to	by the Examiner.	
Priority under	35 U.S.C. §§ 119 and 120		
13)☐ Ackr	lowledgment is made of a claim	for foreign priority under 35 U.S.C	s. § 119(a)-(d) or (f).
a)∏ All	b)☐ Some * c)☐ None of:		
1.	Certified copies of the priority	documents have been received.	
2.	Certified copies of the priority	documents have been received in	Application No
	application from the Intern	of the priority documents have bee ational Bureau (PCT Rule 17.2(a)) n for a list of the certified copies no).
			C. § 119(e) (to a provisional application
a) 🗌		iguage provisional application has	been received.

U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)

Attachment(s)

6) Other:

Application/Control Number: 09/816,790

Art Unit: 1636

DETAILED ACTION

Claims 11-16, 22-25 and 40-51 are pending in the application.

Claims 11-16 and 22-25 are withdrawn from consideration for being directed to nonelected subject matter. Claims 40-51 are currently under examination.

This Office Action is in response to the Amendment filed on 3/4/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/4/03 has been entered.

Response to Amendment

The rejection of claims 31-39 under 35 U.S.C. 112 1st paragraph is moot in light of Applicants' cancellation of the claims.

The rejection of claims 26-30 under 35 U.S.C. 103 (a) is moot in light of Applicants' cancellation of the claims.

Claims 44-49 and 51 are rejected under 35 U.S.C.112 1st paragraph (scope of enablement) for reasons discussed below.

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Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-49 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse whose genome comprises a homozygous disruption of the endogenous sulfotransferase gene, wherein said transgenic mouse lacks production of the functional sulfotransferase protein, and exhibits a behavioral abnormality, does not reasonably provide enablement for a transgenic mouse whose genome comprises a heterozygous disruption of the endogenous sulfotransferase gene. Further, the specification does not support the enablement of a cell or tissue isolated from the transgenic mouse. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The newly added claims 44-49 and 51 are rejected for same reasons as applied to now cancelled claims 31-39 that set forth of the record mailed on 10/23/03 (see pages 3-5).

The nature of the invention is a transgenic mouse comprising a disruption in the sulfotransferase gene, wherein said transgenic mouse lacks production of the functional sulfotransferase protein and exhibits a behavioral abnormality. The invention is further drawn to a cell or tissue isolated from said mouse.

Art Unit: 1636

The specification discloses that only the homozygous knockout mice exhibit a behavioral abnormality including aggressive behavior, hyperactivity and decreased anxiety (see page 59-60). The specification fails to teach whether transgenic mice having heterozygous disruption of the sulfotransferase gene also exhibit same phenotype as the homozygous transgenic mice.

Claims 44-49 encompass heterozygous mouse. The heterozygous mouse comprises one allele having a normal sulfotransferase gene; hence it expresses functional sulfotransferase protein. Therefore, the heterozygous mouse would not be expected to have the phenotype of behavioral abnormality as the homozygous mouse. The claims recite that the transgenic mouse "lack production of functional sulfotransferase protein." The specification does not teach how to make a transgenic mouse having heterozygous disruption of the sulfotransferase gene and lacks functional sulfotransferase protein. The specification also fails to teach how to use a transgenic mouse without the disclosed phenotype. Further, the specification does not teach how to use a cell or tissue isolated from said mouse. The phenotype of the transgenic mouse would not be displayed by a tissue or cell isolated from said mouse because the behavioral abnormality of a cell or tissue cannot be determined by any of the method disclosed in the specification.

Therefore, one skilled of art would have to engage in undue experimentation to determine how to make and use the invention in commensurate with the scope of the claims.

This rejection can be overcome by limiting the claims to a homozygous mouse.

Claims 40-43 and 50 are allowed.

Application/Control Number: 09/816,790

Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D. April 18, 2003

ANNE-MARIE FALK, PH.D PRIMARY EXAMINER

Anne-Marie Falk